

MANUAL BOOK MEDICAL NON CONTACT FOREHEAD THERMOMETER THERM ONE

1. Foreword

Thank you for purchasing Elitech product. Medical No-contact Electronic Forehead Infrared Thermometer Therm One (here in after called the Therm One) is a thermometer which is used for measuring the temperature of human body at forehead by the principle of receiving infrared. According to the human body skin difference, the measuring temperature would be different. When changing the location from two different temperature location, before use, please put the forehead thermometer in the same condition at least 30 minutes, so that the forehead thermometer could be adapted to the ambient temperature. It is mainly applied to household (consumer use). For your correctly use, please make sure you have read this user manual. Please keep it carefully, in case you can refer again someday.

2. Declaration of Conformity

- This device fulfils the provisions of EC directive 93/42/EEC (Medical Device Directive).
- This forehead thermometer meets requirements established in ASTM Standard E1965-98(2009). Full responsibility for the conformance of this product to the standard is assumed by PT. Sindo Prima Alloy.
- This device has been tested and homologated in accordance with EN60601-1-2:2015 for EMC. This does not guarantee in any way that the device will not be affected by electromagnetic interference. Avoid using the device in high electromagnetic environment.

3. Important Safety Information

The warning symbol and cutline mentions in this user manual give guidance of safety and correct method, and avoid harm to your body.

The warning symbol and cutline as follow:

Warning Symbol	Meaning
	It may cause harm to body or mangle article

Warning	
	Prohibit operation. Prohibit operation can be found in or description by words or photo nearby. Symbol in left means "General prohibit"
	Must follow operation Must follow operation can be found in or description by words or photo nearby. Symbol in left means "General must follow operation"

Correct Disposal of This Product	
Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling.	
Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.	
This product does not contain any hazardous substances.	
<ul style="list-style-type: none"> Please don't commix new and old batteries or different brand and type of batteries. Please pull out the batteries if it is not in use for a long time (More than 3 months) 	

Correct Disposal of This Product	
Please set "+, -" pole correctly .	
<ul style="list-style-type: none"> Disobey of above operation may course batteries heat, fluid, or blast, and therefore mangle the product. If battery fluid should get on your skin or clothing, please rinse with plenty of clean water at once. Please don't through batteries in fire! It may course blast. Disposal of discarded batteries should be in accordance with the national regulations for the disposal of discarded batteries. 	

Universality affair	
Use of this thermometer is not intended as a substitute for consultation with your physician. There may be a risk of exasperating the state of an illness by self-estimate.	
Please do not put our products close to the charged object. In order to avoid the possibility of electric shock.	
Disposal of discarded Forehead Thermometer should be in accordance with the national regulations.	
The user should contact the manufacturer if require further advice for using or maintaining your device or to report unexpected operation or events.	
It is necessary to clean the device between uses on different PATIENTS, including methods for rinsing, drying, handling and storage until re-use.	
It can be unsafe to modify the equipment.	
Be careful not to devour small volume items, such as the batteries, screws, etc.	
The accessible materials used in the ME EQUIPMENT have been passed the biological performance test. There are not potential allergic reactions to accessible materials used in the ME EQUIPMENT.	
Don't expose this thermometer to extreme temperature conditions of > 50 °C or <-20 °C.	
Do not apply a strong shock to, drop, step on, or vibrate the main unit.	
Do not drop or knock the device, and do not use if damaged.	
Don't use the device beyond intended use.	
Keep the device away from water and heat, including direct sunlight.	
Do not use a portable phone near the unit.?	
Do not disassemble, repair, or modify the unit.?	
Please use and keep this product with the standard mentions in this manual, Otherwise, It can not measure correctly.	
This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.	
MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS	
Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.	
Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.	
The effects of degraded sensors that can degrade performance or cause other problems such as non-working . The effects caused by pets, pests or children that can degrade performance or cause other problems such as non-working . Please contact the manufacturer if the accuracy is not sure.	

Meanings of Symbols	
Signs	Notes on the signs
	Attention! Please refer to the accompanying document (the Manual Book)
P/N	Material code by manufacturer
	Type BF Applied Part
	Class III
	Refer to instruction manual
	Refer to instruction for use
	Manufacturer
LOT	Specific batch code
SN	Serial Number

	This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.
IP22	IP22: The first number 2: Protected against access to hazardous parts with a finger, and the jointed test finger of 12 mm Ø, 80 mm length, shall have adequate clearance from hazardous parts .And protectedagainst solid foreign objects of 12,5 mm Ø and greater. The second number: Protected against vertically falling water drops when enclosure tilted up to 15 °.Vertically falling drops shall have no harmful effects when the enclosure is tilted at any angle up to 15°on either side of the vertical.
	Bateray
	This way up
	Fragile, handle with care
	Keep away from rain
	Humidity limit
	Temperature limit
	Atmospheric pressure limit

	43°C (93.2°F ~ 109.4°F) Surface temperature : 0°C ~ 100°C (32°F ~ 212°F)
Accuracy	22.0°C ~ 42.0°C : ± 0.3°C < 22.0°C : ± 0.5°C > 42.0°C : ± 0.5°C
Resolution	0.1°C (0.1°F)
Reading unit	°C/°F
Measure time	≤1 second
Memory	32 set
Weight	125 g
Dimension	43 x 90 x 145 mm
Operating	Operating
Humidity	86 ~ 106 kPa
Transportasi dan Penyimpanan	Atmosphere -20°C ~ 50°C Temperature Storage Humidity 86 ~ 106 kPa Storage

WARNING:

This unit has been thoroughly tested and inspected to assure proper performance and operation!

The performance of the instrument may be adversely affected the following occur:

- Operation outside of the specified subject temperature t.
- Operation outside of the specified ambient temperature and humidity ranges
- Storage outside of the specified ambient temperature and humidity ranges
- Mechanical shock may be adversely affected performance of the instrument.

6. Intended Use

The forehead thermometer is designed for body surface and forehead temperature measurement for infant and adults without contact to human body. The forehead thermometer can also be used to measure the temperature of a baby-bottle or bath or room temperature (by using the surface mode).

Normal Temperatures According To Measurement Method

Measurement Method	Normal Temp °C	Normal Temp °F
Rectal	36.6 to 38	97.8 to 100.4
Oral	35.5 to 37.5	95.9 to 99.5
Axillary	34.7 to 37.3	94.4 to 99.1
Ear	35.8 to 38	96.4 96.4 to 100.4

The temperature of the human body varies throughout the day. It can also be influenced by numerous external factors: age, sex, type and thickness of skin. Normal Temperatures According To Age

Age	Temp °C	Temp °F
0-2 years	36.4 to 38.0	97.5 to 100.4
3-10 years	36.1 to 37.8	97.0 to 100.0
11-65 years	35.9 to 37.6	96.6 to 99.7
> 65 years	35.8 to 37.5	96.4 to 99.5

Attention: ASTM laboratory accuracy requirements in the display of 37 to 39°C(98 to 102°F) for Skin IR thermometers is ±0.3°C(± 0.5°F) , whereas for mercury in-glass and electronic thermometers, the requirement per ASTM Standards E667-86 and 1112-86 is ±0.1°C(± 0.2°F) .

Manufacturer will make available upon request specific instructions for tests to determine the laboratory error, clinical bias and clinical repeatability.

When you need to clinical accuracy characteristics and procedures ,please contact with the local distributors obtain from our company.

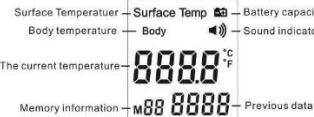
Model	Therm One
Battery	2 battery "AA"
Display	1.3" with backlight
Power	≤ 50mW
Range of measurement	Body temperature : 34°C ~

7. Part Identification (As Picture)

7.1 Basic Components



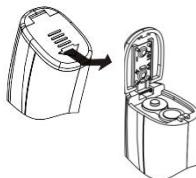
7.2 Display



8. Operation and Setting

8.1 Installing or replacing the batteries

- Push the battery cover back, open the cover from the body.
- Insert two "AA" batteries as indicated in the battery compartment and then replace the battery cover.



8.2 Setting method

Keep pressing "SET" key and hold for 3 seconds into the setting mode.

8.2.1 Select measurement unit--Menu F1

Enter into setting mode, the LCD displays "F1", press "+" key to select "F" unit, press "-" key to select "C" unit.

8.2.2 Warning value setting---Menu F2 (Default 37.8 °C (100.4°F))

Enter into setting mode, short press "SET" key twice, the LCD displays "F2", then press "+" key to increase the setting value 0.1°C(0.1°F), press "-" key to reduce the setting value 0.1°C(0.1°F).

8.2.3 Offset value setting---Menu F3(Default 0.0 °C (0.0°F))

Enter into setting mode, press "SET" key triple, the LCD display "F3", then press "+" key to increase the setting value 0.1°C(0.1°F), press "-" key to reduce the setting value 0.1°C(0.1°F).

8.2.4 Sound notification setting

Enter into setting mode, press "SET" key four times, the LCD display "F4", then press "+" key to turn on the sound notification function, press "-" key to turn off the sound notification function.

8.2.5 Backlight setting---Menu F5

Enter into setting mode, press "SET" key five times, the LCD display "F5", then press "+" key to turn on the backlight function, press "-" key to turn off the backlight function.

8.2.6 Exit setting mode

Press "SET" key until shutdown.

8.3 Advice For The 1st Use

For stable and reliable results, it is essential to check the forehead thermometer and change as needed, as follows:

8.3.1 Take the temperature of the same person using a conventional thermometer; you will get 37.0°C(98.6°F) for instance.

8.3.2 Take the temperature of the same person using the forehead thermometer keeping the 50 to 150 mm distance between the thermometer and the forehead (Take care to remove any obstacle which could alter the measurement (hair, perspiration...). If you get 37.0 °C (98.6 °F), the Non-contact body infrared Thermometer is properly set and ready for use. If you get a lower temperature, 36.4°C(97.4°F) for example, your difference is 0.6°C (1.2°F), you should adjust the temperature on the forehead Thermometer Body infrared Thermometer and add the difference, i.e. 0.6°C (1.2°F). To do it, press the "SET" button for 3 seconds, the screen displays F1, press "SET" button again until you get F3, press "+"

button in order to add the difference (in our example, 0.6°C (1.2°F)).

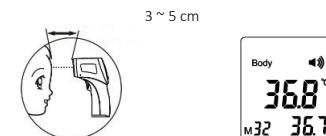
8.3.3 To check, take the temperature again using the Non-contact body infrared Thermometer.

Caution : This setting applies only to Body mode

8.4 Correct measurement

8.4.1 Measurement body temperature

Hold the forehead thermometer, leave one finger in front of the button, keep transducer window at human's forehead, leaving a distance of 30 ~ 50mm from the forehead. Press the button, and the thermometer will start up automatically and display the measurement result, as shown in the figure below:



8.4.2 Measurement ambient temperature

Hold the thermometer, leave one finger in front of the button, Level the detection window face to the place where you want to measure, and then press button. The thermometer will start up automatically and display the measurement result, as shown in the figure below:

Cautions :

- After replaced the batteries or move the thermometer to a new place ,It is suggested to lay the forehead thermometer aside at least 30 minutes before using, so that you can measure temperature more accurately.
- If the measurement is made without an effective distance or an deflection of the central position of the measured object, a deflection from actual temperature may cause. It is suggested to repeat the measurement once or more.
- While measuring, it is suggested to focus the detection window at the forehead, and press the measurement button in front of the handle, scan the forehead around, so that it can measure the highest and lowest temperature of the forehead.
- It may affect the accuracy of measurements when the forehead is covered by hair, perspiration, cap or scarf.

8.4.3 Selecting measuring body temperature or surface temperature

Turn on the thermometer, press "SET" key to select body temperature measurement mode or surface temperature measurement mode.

8.4.4 Data Memory

In measuring mode, press "+" or "-" key to view measurement result. "+" key for page up, "-" key for page down. Press the "+" or "-" key and hold for 2 seconds, the result switches quickly.

9. Troubleshooting

Error Symbol	Cause	Processing Method
	Low battery voltage	Exchange new batteries
	System fault	Return the selling point
	Ambient temperature too high	Please follow user manual user in the Ambient temperature.

	Ambient temperature too low	
	Measuring temperature too high	Stop measuring
	Measuring temperature too low	

10. Care and Maintenance

- The protective glass over the lens is the most important and fragile part of the thermometer, please take great care of it.
- Do not recharge non rechargeable batteries, do not throw in fire.
- Do not expose the thermometer to sunlight or water.
- The Infrared Sensor is the most precise part, must be protected carefully.
- Clean and Disinfect the device with a cotton bud lightly moistened with 70% alcohol.
- Do not clean the device with corrosive detergent.
- Keep the device in a dry environment, and keep it away from dust and direct sunlight.
- The main unit is not waterproof. Be careful when handling this unit so that no liquid (alcohol, water, or hot water) will get into the main unit.
- If the infrared sensor becomes dirty, lightly wipe it with a soft dry cloth.
- It is regular recommended to do the recalibration every two years to ensure functioning correct

EXPECTED SERVICED LIFE: 2 YEARS.

The typical service life of the new and unused batteries is 10000 measurements for the operation time is 10s.

WARNING: Do not modify this equipment without authorization from manufacturer.

Manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair .

11. Quality Promised and Service

The guarantee time is two years after you buy the device.

Notice : If the device is broken by the non-formal used or disassemble by you, the device can not be in the guarantee range.

Tips: Please keep the guarantee card and the buying receipt, which is very useful when you need to amend it.

12. Attachment List

- One set of Electronic Forehead Infrared Thermometer.
- One set of user manual.
- One set of the Warranty certificate.
- 2x1.5 AA Batteries.

13. Safety Classification of ME EQUIPMENT

Protection against electric shock	Internally powered ME equipment
Applied part	Type BF applied part, including the whole forehead thermometer
Protection against harmful ingress of water or particulate matter	IP22
Mode of operation	Continuous operation

Note: Not intended to be sterilized.
Not for use in an OXYGEN RICH ENVIRONMENT

14. EMC Precaution

1. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS
2. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment.

Note:

As indicated in Table 6 of IEC 60601-1-2:2015 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m.

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